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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/286,530	04/05/1999	L. LAWRENCE CHAPOY	7651/1239	5116

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GARDNER GROFF, P.C.
PAPER MILL VILLAGE, BUILDING 23
600 VILLAGE TRACE
SUITE 300
MARIETTA, GA 30067

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/286,530

Applicant(s)

CHAPOY ET AL.

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-17, 19-22, 24-40, and 42-55 is/are pending in the application.
- 4a) Of the above claim(s) 24-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-17, 19-22, 40 and 42-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims 24-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6 of October 6, 2000.

New claims 52 and 53 have been renumbered as claims 54 and 55 respectively because claims 52 and 53 were originally added to the claim set by Amendment A dated October 23, 2000.

Claim Objections

Claim 40 is objected to because of the following informalities:

On lines 5-6 of claim 40, "the surrounding tissue" lacks antecedent basis from earlier in the claim. The Examiner suggests using "the human tissue" for "the surrounding tissue" in order to overcome this objection.

On lines 8-10 of claim 40, the language "a unitary structure with having the anchoring region" is grammatically awkward (emphasis added). Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-14, 40, 42, and 44-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al (US 6,158,862) in view of Patel (US 5,252,262) and

Kearns et al (US 5,074,942). Patel et al discloses an apparently monolithically produced intraocular lens with haptics of the same material, but fails to disclose a coating on at least the distal portions of the haptics as claimed; see Figure 2 and column 4, lines 7-29.

However, Patel ('262) teaches that it was known to coat haptics on similar intraocular lenses with polyimide in order prevent dye or pigment leakage; see the whole document, especially Figures 26-27 and column 4, lines 15-57.

Furthermore, Kearns teaches that it was known to make monolithic lenses and haptics from the same material; see the abstract.

Hence, it is the Examiner's position that it would have been obvious to make the intraocular lens monolithically as taught by Kearns, for the reasons that Kearns does the same, and to clear coat at least the haptics of Patel et al in order to prevent dye leakage which is a concern to Patel et al as well; see column 4, lines 7-14.

With regard to claims 2, 9-14 and 44-53, the product-by-process steps are only given weight to the extent that they affect the final product with little burden on the Examiner's part to meet the claim language; see MPEP 2113, which is incorporated herein by reference thereto. Hence, it is the Examiner's position that the claim product-by-process limitations result in an identical, or alternatively, a substantially identical product to that disclosed by Patel et al as modified by Patel such that the claims are clearly unpatentable thereover.

With regard to claim 6, HEMA is synonymous with 2-hydroxyethylmethacrylate such that the claim language is fully met.

With regard to claim 8, the 550 nm or 400 nm wavelength range is within the UV radiation range, and thus, the dye of Patel et al is a UV absorbing compound to the extent required by the claims; see Patel et al on column 4, lines 1-29.

With regard to claim 40 and 42-53, the polyimide as claimed is the same material as that set forth by Patel, such that it would inherently have the same fibrosis promotion affect.

With regard to claim 54, the Examiner has interpreted "hydroacrylic acid" as being another way of writing "hydroxyacrylic acid." Therefore, since HEMA or hydroxyethyl methacrylate is a type of hydroxyacrylic acid, the Examiner interprets Patel ('862) as disclosing the claimed material; see column 4, lines 7-14.

Claims 15-17, 19-22, 43, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al, Kearns et al and Patel ('262) as applied to claims 1, 2, 4-14, 40, 42, and 44-53 above, and further in view of Cumming (US 5,047,051). Patel et al meets the claim language except for the footplate or an opposing set of plates with grooves as claimed. Cumming, however, teaches that it was known to make haptics into opposing plate or footplate forms with grooves; see the figures and the rest of the document. Hence, it is the Examiner's position that it would have been obvious to make the polyimide coated haptics of Patel et al as modified by Patel into a plate form and to coat the entire haptics thereof with polyamide for the same reasons that Cumming forms his haptics into that form.

With regard to claim 55, the Examiner has interpreted "hydroacrylic acid" as being another way of writing "hydroxyacrylic acid." Therefore, since HEMA or

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hydroxyethyl methacrylate is a type of hydroxyacrylic acid, the Examiner interprets Patel ('862) as disclosing the claimed material; see column 4, lines 7-14.

Claims 1, 2, 5, 7-14, 20, 22, 40, 42, and 44-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearns et al (US 5,074,942) in view of Patel (US 5,252,262).

Kearns discloses a monolithically produced intraocular lens where the lens and haptic have the same composition as required by the present claims; see the abstract and the figures. The entire device can be made of polymethylmethacrylate or PMMA; see for example, column 3, lines 24-56. It is noted that the haptics are colored and there is a concern that the dye may leak into the eye; see column 6, lines 16-48. However, Kearns fails to disclose that the haptics can be coated with a polyimide coating as claimed.

However, Patel teaches that it was known to coat the haptic with a clear coating of the PMMA, polyethylene or polyimide in order to prevent leaking of the dye into the eye; see column 4, lines 29-34.

Therefore, it is the Examiner's position that it would have been obvious to clear coat the colored haptics of Kearns with a polyimide coating as a precaution against dye leakage.

Response to Arguments

Applicant's arguments filed July 3, 2003 have been fully considered but they are not persuasive.

Applicant traverses the obviousness rejections by attacking the references individually. One cannot show nonobviousness by attacking references individually where the rejections are based upon combinations of references. *In re Keller* 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc* 800 F.2d 1091, 231 USPQ 275 (Fed. Cir. 1986).

Applicant argues that the applied prior art does not discuss anything pertaining to fibrosis promotion effects. However, the rejection uses a different motivation for the combination. The reason for the coating in Patel need not be the same as that of Applicant's invention in order for the claims to be considered obvious thereover; see MPEP 2144 which is incorporated herein by reference thereto and see *In re Linter* 173 USPQ 560 (CCPA 1972).

Similarly, Applicant argues that the fibrosis promotion was not within the knowledge of the prior art. However, the Examiner asserts that "prima facie obviousness is not rebutted by merely recognizing additional advantages or latent properties present in the prior art. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention"; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA) 1979"; see MPEP 2145 II.

The Applicant also argues that there is no motivation to combine the references. However, the motivation to combine is clearly set forth in each rejection; e.g. "to prevent dye leakage" or "for the same reasons that Cummings forms his haptics in that form." All the reasons used were within the knowledge available to one of ordinary skill in the art; see MPEP 2145 (X) (A), which is incorporated herein by reference.

Finally, the Applicants argue that there is no reasonable expectation of success to increase fibrosis. However, the Examiner asserts that this is not a sufficient issue since the coating is for a different reason and the claim and specification does not set forth a sufficient amount to promote fibrosis. Even if the claims did set forth a sufficient amount and there was support for the same, the range for the sufficient amount would have to be outside the range disclosed by Patel for preventing dye leakage. It appears that the Applicant merely found a new property for an obvious combination.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chang et al (US 5,712,327) is cited because it uses "hydroacrylic" monomer units in a polymer of a contact lens; see claim 7. It may be that "hydroacrylic" is a typographical error for the more frequently used term "hydroxy acrylic" term.

Rossi (US 4,135,887) is cited to show that the term "hydroacrylic acid" is used to refer to beta lactones in an unrelated art; see column 2, line 67 to column 3, line 15.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.


Paul Prebilic
Primary Examiner
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